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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,665	07/01/2003	Jacob Nielsen	10165-022-999	5726

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222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER	
MERTZ, PREMA MARIA	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 06/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/612,665	NIELSEN ET AL.	
	Examiner	Art Unit	
	Prema M. Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-68 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-68 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-12, 14-44, 51-53, 57-58, are drawn to a tissue protective cytokine, classified in Class 530, subclass 351.

Group II. Claims 45-50, are drawn to a nucleic acid, a vector, and a host cell, classified in Class 536, subclass 23.51.

Group III. Claims 54-56, are drawn to a method of treatment by administering a tissue protective cytokine in vitro, classified in Class 435, subclass 7.1.

Group IV. Claims 54-56, are drawn to a method of treatment by administering a tissue protective cytokine in vivo, classified in Class 424, subclass 85.1.

Group V. Claims 59-62, are drawn to a method of facilitating the transcytosis of a molecule by administering the molecule with a tissue protective cytokine, classified in Class 424, subclass 85.1.

Group VI. Claims 66-68, are drawn to a recombinant tissue protective cytokine in association with another molecule, classified in Class 530, subclass 402.

Group VII. Claim 13, is drawn to a recombinant tissue protective cytokine responsive cell, classified in Class 435, subclass 325.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-II and VI-VII, are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function and each has

an independent utility, that is distinct for each invention which cannot be exchanged. The polynucleotide of invention II can be used to make a hybridization probe or can be used in the production of the specific protein of interest. The proteins of invention I can be used as probes, or used therapeutically or diagnostically, e.g. in screening. The proteins of invention VI which are functionally and structurally different from the protein of invention I can be used as probes, or used therapeutically or diagnostically. The cells of invention VII can be used in cell transplantation.

Inventions I and III-V are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the protein product of invention I can also be used diagnostically.

Inventions II and III-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions VII and III-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions III-V are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials, process steps and goals.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter as defined by MPEP § 808.02, the Examiner has *prima facie* shown a serious burden of search (see MPEP § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

2. Claim 1 links claims 2-44. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claims. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP 804.01.

Election of Species

3. This application contains claims directed to the following patentably distinct species of the claimed invention:

Applicants are required to elect one of species of tissue protective cytokine polypeptide selected from:

(i) any one substitution of an amino acid at a particular amino acid in SEQ ID NO:10; and

(ii) any one deletion of an amino acid in SEQ ID NO:10.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims1 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. This application contains claims directed to the following patentably distinct species of cell of the claimed invention:

Applicants are required to elect one of species of cell selected from:

(i) photoreceptor;

(ii) ganglion;

(iii) bipolar;

(iv) horizontal;

(v) amacrine;

(vi) Muieller;

(vii) myocardium;

(viii) pace maker;

(ix) sinoatrial node;

(x) sinus node;

(xi) atrioventricular node;

(xii) bundle of His;

(xiii) hepatocyte;

(xiv) stellate;

(xv) Kupffer;

(xvi) mesangial;

(xvii) goblet;

(xviii) intestinal gland;

(xix) enteral endocrine;

(xx) glomerulosa;

(xxi) fasciculate;

(xxii) reticularis;

(xxiii) chromaffin;

(xxiv) pericyte;

(xxv) Leydig;

(xxvi) Sertoli;

(xxvii) sperm;

(xxviii) Graffian follicles;

(xxix) primordial follicles;

(xxx) endometrial stroma; and

(xxxi)endometrial cell.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of cell for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims1-6 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. This application contains claims directed to the following patentably distinct species of cytokine of the claimed invention:

Applicants are required to elect one of species of tissue protective cytokine polypeptide selected from:

i. a cytokine having a reduced number or no sialic acid moieties;

ii. a cytokine having a reduced number or no N-linked or O-linked carbohydrates;

iii. a cytokine having at least a reduced carbohydrate content by virtue of treatment of native cytokine with at least one glycosidase;

iv. a cytokine having at least one or more oxidized carbohydrates;

v. a cytokine having at least one or more oxidized carbohydrates and is chemically reduced;

vi. a cytokine having at least one or more modified arginine residues;

vii. a cytokine having at least one or more modified lysine residues or a modification of the N-terminal amino group of a cytokine molecule;

viii. a cytokine having at least a modified tyrosine residue;

ix. a cytokine having at least a modified aspartic acid or glutamic acid residue;

x. a cytokine having at a modified tryptophan residue;

xi. a cytokine having at least one amino acid group removed;

xii. a cytokine having at least one opening of at least one of the cystine linkages in the cytokine molecule;

xiii. a truncated cytokine;

xiv. a cytokine having at least one polyethylene glycol molecule attached;

xv. a cytokine having at least one fatty acid attached;

xvi. a cytokine having a non-mammalian glycosylation pattern by virtue of the expression of a recombinant cytokine in non-mammalian cells; and

xvi. a cytokine having at least one histidine tagged amino acid to facilitate purification.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims1-6 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable

thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. This application contains claims directed to the following patentably distinct species of endothelial cell barrier of the claimed invention:

Applicants are required to elect one of species of barrier selected from:

(i) blood-brain barrier;

(ii) blood-eye barrier;

(iii) blood testes barrier;

(iv) blood-ovary barrier; and

(v) blood-uterus barrier.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of barrier for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-6 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. This application contains claims directed to the following patentably distinct species of cell of the claimed invention:

Applicants are required to elect one of species of cell selected from:

(i) neuronal;

(ii) muscle;

(iii) heart;

(iv) lung;

(v) liver;

(vi) kidney;

(vii) small intestine;

(viii) adrenal cortex;

(ix) adrenal medulla;

(x) capillary;

(xi) endothelial;

(xii) testis;

(xiii) ovary;

(xiv) endometrial; or

(xv)stem cell.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims1-6 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8. This application contains claims directed to the following patentably distinct species of cytokine of the claimed invention:

Applicants are required to elect one of species of tissue protective cytokine selected from:

(i) asialoerythropoietin;

(ii) hyposialyated erythropoietin;

(iii) hypersialylated erythropoietin;

(iv)periodate-oxidized erythropoietin;

(v) R-glyoxal erythropoietin;

(vi) phenylglyoxal-erythropoietin;

(vii)erythropoietin in which arginine is modified with 2,3-butanedione;

(viii) erythropoietin in which arginine is modified with cyclohexadione;

(ix) erythropoietin in which arginine is modified with 3-deoxyglucosone;

(x) glucitolyl lysine erythropoietin;

(xi) fructosyl lysine erythropoietin;

(xii) alpha-N-carbamoylerythropoietin;

(xiii) N-epsilon-carbamoyl erythropoietin;

(xiv) alpha-N-carbamoyl, N-epsilon-carbamoyl erythropoietin;

(xv) alpha-N-carbamoylasialoerythropoietin;

(xvi) N-epsilon-crbamoylasialoerythropoietin;

(xvii) alpha-N-carbamoyl, N-epsilon-carbamoylasialoerythropoietin;

(xviii) alpha-N-carbamoylhyposialoerythropoietin;

(xix) N-epsilon-carbamoylhyposialoerythropoietin;

(xx) alpha-N-carbamoyl, N-epsilon-carbamoylhyposialoerythropoietin;

(xxi) alpha-N-acetylerythropoietin;

(xxii) N-epsilon-acetylerythropoietin;

(xxiii) alpha-N-acetyl, N-epsilon-acetylerythropoietin;

(xxiv) alpha-N-acetylasialoerytropoietin;

(xxv) N-epsilon-acetylasialoerythropoietin;

(xxvi) alpha-N-acetyl, N-epsilon-acetylasialoerythropoietin;

(xxvii) alpha-N-acetylhyposialoerythropoietin;

(xxviii) alpha-N-acetyl, N-epsilon-acetylhyposialoerythropoietin;

(xxix) alpha-N-succinylerythropoietin;

(xxx) N-epsilon-succinylerythropoietin;

(xxxi) alpha-N-succinyl, N-epsilon-succinylerythropoietin;

(xxxii) alpha-N-succinylasialoerythropoietin;

(xxxiv) N-epsilon-succinylasialoerythropoietin;

(xxxv) alpha-N-succinyl, N-epsilon-succinylasialoerythropoietin;

(xxxvi) alpha-N-succinylhyposialoerythropoietin;

(xxxvii) N-epsilon-succinylhyposialoerythropoietin;

(xxxviii) alpha-N-succinyl, N-epsilon-succinylhyposialoerythropoietin;

(xxxix)erythropoietin modified at a lysine residue;

(xl) erythropoietin modified at a aspartic acid residue;

(xli) erythropoietin modified at a glutamic acid residue; or

(xlii) N-epsilon-acetylhyposialoerythropoietin.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims1-6 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

9. This application contains claims directed to the following patentably distinct species of activity lacking from the instant cytokine of the claimed invention:

Applicants are required to elect one of species of activity selected from:

(i) increasing hematocrit;

(ii) vasoactive action;

(iii) hyperactivating platelets;

(iv) pro-coagulant activities; and

(v) increasing production of thrombocytes,

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims1-6 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable

thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

10. This application contains claims directed to the following patentably distinct species of injury of the claimed invention:

Applicants are required to elect one of species of injury caused by a disorder selected from:

(i) a seizure disorder;

(ii) multiple sclerosis;

(iii) stroke;

(iv) hypotension;

(v) cardiac arrest;

(vi) ischemia;

(vii) myocardial infarction;

(viii) inflammation;

(ix) age-related loss of cognitive function;

(x) radiation damage;

(xi) cerebral palsy;

(xii) neurodegenerative disease;

(xiii) Alzheimer's disease;

(xiv) Parkinson's disease;

(xv) Leigh disease;

(xvi) AIDS;

(xvii) memory loss;

(xviii) amyotrophic lateral sclerosis;

(xix) alcoholism;

(xx) mood disorder;

(xxi) anxiety disorder;

(xxii) attention deficit disorder;

(xxiii) autism;

(xxiv) Creutzfeld-Jakob disease;

(xxv) brain or spinal cord trauma;

(xxvi) brain or spinal cord ischemia;

(xxvii) heart-lung bypass;

(xxviii) chronic heart failure;

(xxix) macular degeneration;

(xxx)diabetic neuropathy;

(xxxi) diabetic retinopathy;

(xxxii) glaucoma;

(xxxiii) retinal ischemia;

(xxxiv) retinal trauma ; or

(xxxv) dementia.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims1-6 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to

be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

11. This application contains claims directed to the following patentably distinct species of molecule to be associated with a cytokine for transport via transcytosis across an endothelial cell barrier of the claimed invention:

Applicants are required to elect one of species of molecule selected from:

(i) receptor agonist;

(ii) receptor antagonist;

(iii) hormone;

(iv) a neurotrophic factor;

(v) an antimicrobial agent;

(vi) a radiopharmaceutical;

(vii) an antisense oligonucleotide;

(viii) an antibody;

(ix) an immunosuppressant;

(x) a dye;

(ix) a marker; or

(x) an anti-cancer drug.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims1-6 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

12. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend**

from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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